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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,455	MEIR, ROSENBERG	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41, 43-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41, 43-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-24, 38-44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 6,248,080 to Miesel et al, further in view of US 7,371,223 to Couvillon, Jr. et al.

In the specification and figures, Cowan discloses the device substantially as claimed by applicant. With regard to claims 1, 18, 19, 40, Cowan discloses an implantable medical device 20 comprising a housing 24, valve 50 disposed within the housing, a pressure sensor or valve-gauge assembly 52 disposed within the housing downstream of the valve, and a CPU or microprocessor associated with element 52 disposed within the housing and connected to the valve-gauge assembly 52. Cowan discloses that valve-gauge assembly 52 comprises a pressure sensor (indicating it is contained within housing 24) *and* a ventricular pressure gauge 52 (see FIG 1, columns 3-4, column 5, lines 11-20). Accordingly, Cowan teaches a valve and pressure sensor (valve-gauge assembly 52) disposed within the housing 24 downstream of valve 50.

Cowan fails to disclose a pressure sensor upstream of the valve within the housing. However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device

such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement 52 downstream of the valve as disclosed by Cowan to a location upstream of the valve 50 in order to diagnose valve performance.

Cowan and Miesel fail to disclose that the pressure sensors and controllers are non-invasively wirelessly powered. However, Couvillon discloses an implantable fluid control device that may use waveform data sent to a receiver that powers an implanted component in order to reduce the size of the control unit (see column 12, lines 28-39). It would have been obvious to one having ordinary skill in the art at the time of invention to use wireless, non-invasive power, such as that disclosed by Couvillon, to supply power to the apparatus suggested by Cowan and Miesel in order to reduce the size of the controller, as taught by Couvillon.

With regard to claims 2-3, 9, the CPU or valve-gauge assembly with processing unit 52 disclosed by Cowan is electrically connected to the pressure sensors (see

columns 5-6, FIG 1). The valve-gauge assembly is connected to transmitter 64 that transmits information to an external computing device (see column 6, lines 1-15).

With regard to claims 4, 5, 10, and 14, applicant claims that the CPU comprises a "means for calculating" a particular parameter. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis (see MPEP § 2181):

a. the claim limitations must use the phrase "means for " or "step for; "

b. the "means for " or "step for " must be modified by functional language; and

c. the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant has satisfied all three prongs of the test and the Examiner has turned to the specification for clarification.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure… described in the specification and equivalents thereof." See MPEP 2181(II). In paragraph 0008 of US 2004/0260229, applicant discloses that the CPU compares values generated by the pressure sensors to generate a differential pressure. It is the position of the Examiner that this disclosure indicates that the "means for calculating" comprises a programmed algorithm. Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52, 54 and is programmed with various criteria to determine whether the valve should be

opened or closed (see column 5, lines 11-26). Such programs are considered by the Examiner to be functional equivalents of the algorithm disclosed by applicant, since differential pressure values are known in the art to control valve movement. Accordingly, the disclosure of Cowan suggests the apparatus of applicant's claims 4, 5, 10, and 14.

With regard to claims 6-8, Cowan discloses a first catheter 28 fluidly connected to housing 24 upstream of valve 50 with a pressure sensor 54 disposed within the catheter 34 and connected to the CPU or valve-gauge assembly 52 (see FIG 1).

With regard to claims 11-13, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan fails to disclose a fourth pressure sensor on second catheter 32. However, However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor

arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in order to diagnose blockages throughout the system.

With regard to claim 20, Cowan and Meisel fail to disclose that the CPU is located outside the housing 24. It has been held that mere rearrangement of the parts of a device found in the prior art is within the skill of a worker in the art, especially if the device with the instantly claimed arrangement would not perform differently than the prior art device. See MPEP 2144.04(IV)(B). In the instant case, applicant has not stated that the location of the CPU outside the housing is for any particular purpose or solves any particular problem. It is the position of the Examiner that the location of the CPU does not affect the performance of the device either as suggested by the prior art or as claimed by applicant. Accordingly, the claimed apparatus is unpatentable over the prior art of record.

With regard to claims 21, 24, 38, and 39, Cowan discloses a first pressure sensor 54 upstream of the valve 50. Cowan also discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52 (contained entirely within the housing), 54 and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26) and may wirelessly transmit data to an external device (see column 6, lines 1-15). Cowan fails to disclose a pressure sensor upstream of the valve within the housing. However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see

column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement 52 downstream of the valve as disclosed by Cowan to a location upstream of the valve 50 in order to diagnose valve performance using the programmed CPU and wireless communication disclosed by Cowan.

With regard to claims 22-23, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52, 54 and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26) and may wirelessly transmit data to an external device (see column 6, lines 1-15). Cowan fails to disclose a fourth pressure sensor on second catheter 32. However, However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11,

lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in order to diagnose blockages throughout the system.

With regard to claims 41, 43, 44 and 46, Cowan and Miesel suggest the apparatus as claimed with the exception of the components disposed on the same substrate. Applicant has not shown that the location of the components on the same substrate is for any particular purpose or solves any particular problem. It is the position of the Examiner that the location of the components on the same substrate does not affect the performance of the device either as suggested by the prior art or as claimed by applicant. Accordingly, the claimed apparatus is unpatentable over the prior art of record.

3. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 6,248,080 to Miesel et al, in view of US 7,371,223 to Couvillon, Jr. et al, further in view of US 2003/0004495 to Saul et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by Applicant (see rejection above).

With regard to claims 15-17, applicant claims that the CPU "is powered" by a particular technology. Such limitations set forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, Applicant provides no structural limitation that allows for such diverse power methods. However, the cited prior art does not suggest that it may be powered in such a fashion. Saul discloses a fluid management apparatus that uses RF energy, optical energy, "or the like," which may include acoustic energy, to power a battery connected to a valve. It has been held that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR International Co. v. Teleflex Inc.,* 127 S.Ct. 1727, 1739 (2007). In the instant case, it is the position of the Examiner that since all the claimed elements are known in the art, it would have been obvious to one having ordinary skill in the art at the time of invention to add the external power sources disclosed by Saul to the fluid management apparatus suggested by the cited prior art, yielding only the predictable result of an implantable fluid management device that may be powered by wireless sources.

4. Claims 25-30, 37, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman, further in view of US 7,371,223 to Couvillon, Jr. et al.

In the specification and figures, Cowan discloses the apparatus and method substantially as claimed by applicant. With regard to claim 25, Cowan discloses an implantable medical device 20 comprising a housing 24, valve 50 disposed within the housing, a pressure sensor 52 disposed within the housing downstream of the valve, and a microprocessor associated with element 52 disposed within the housing and connected to the pressure sensor (see FIG 1, columns 3-4).

Cowan fails to disclose that the pressure sensor 52 comprises a differential pressure sensor. However, Cosman discloses an implantable differential pressure sensor that upon undergoing a conformational change, transmits that information to an external device. The device allows for the accurate measurement of a difference in pressure across a membrane (see columns 1-2). The combination of the shunt apparatus disclosed by Cowan with the differential pressure sensor disclosed by Cosman by known methods yields only predictable results—that is, a shunt system that relies on a single sensor, rather than two sensors, to generate a differential pressure measurement to operate an associated shunt valve. Accordingly, it is the position of the Examiner that taken together, the references reasonably suggest the claimed invention to a person of ordinary skill in the art.

Cowan and Cosman fail to disclose that the pressure sensors and controllers are non-invasively wirelessly powered. However, Couvillon discloses an implantable fluid

control device that may use waveform data sent to a receiver that powers an implanted component in order to reduce the size of the control unit (see column 12, lines 28-39). It would have been obvious to one having ordinary skill in the art at the time of invention to use wireless, non-invasive power, such as that disclosed by Couvillon, to supply power to the apparatus suggested by Cowan and Cosman in order to reduce the size of the controller, as taught by Couvillon.

With regard to claim 26, both Cowan and Cosman disclose that the apparatus is connected to an apparatus that transmits information to an external computing device (see Cowan column 6, lines 1-15, Cosman column 1, lines 13-24).

With regard to claims 27-30, Cowan discloses a first catheter 28 fluidly connected to housing 24 upstream of valve 50 with a pressure sensor 54 disposed within the catheter 34 and connected to the CPU or valve-gauge assembly 52 (see FIG 1).

With regard to claim 37, Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressure sensors and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26) and may wirelessly transmit data to an external device (see column 6, lines 1-15). The combination of the method disclosed by Cowan with the differential pressure sensor disclosed by Cosman by known methods yields only predictable results—that is, a shunt system and method that relies on a single sensor, rather than two sensors, to generate a differential pressure measurement to operate an associated shunt valve. Accordingly, it is the position of the Examiner that

taken together, the references reasonably suggest the claimed invention to a person of ordinary skill in the art.

With regard to claim 45, Cowan and Cosman suggest the apparatus as claimed with the exception of the components disposed on the same substrate. Applicant has not shown that the location of the components on the same substrate is for any particular purpose or solves any particular problem. It is the position of the Examiner that the location of the components on the same substrate does not affect the performance of the device either as suggested by the prior art or as claimed by applicant. Accordingly, the claimed apparatus is unpatentable over the prior art of record.

5. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman, in view of US 7,371,223 to Couvillon, Jr. et al, further in view of US 2003/0004495 to Saul et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by Applicant (see rejection above).

With regard to claims 34-36, applicant claims that the CPU "is powered" by a particular technology. Such limitations set forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, Applicant provides no structural limitation that allows

for such diverse power methods. However, the cited prior art does not suggest that it may be powered in such a fashion. Saul discloses a fluid management apparatus that uses RF energy, optical energy, "or the like," which may include acoustic energy, to power a battery connected to a valve. It has been held that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR International Co. v. Teleflex Inc.,* 127 S.Ct. 1727, 1739 (2007). In the instant case, it is the position of the Examiner that since all the claimed elements are known in the art, it would have been obvious to one having ordinary skill in the art at the time of invention to add the external power sources disclosed by Saul to the fluid management apparatus suggested by the cited prior art, yielding only the predictable result of an implantable fluid management device that may be powered by wireless sources.

6. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman, in view of US 7,731,223 to Couvillon, Jr. et al, further in view of US 6,428,080 to Miesel.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by applicant (see rejection above) with the exception of an additional pressure sensor located on a second catheter. With regard to claims 11-13, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan fails to disclose a fourth pressure sensor on second catheter 32.

However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in the apparatus suggested by Cowan and Cosman in order to diagnose blockages throughout the system.

Response to Arguments

7. Applicant's arguments filed 31 July 2009 have been entered and fully considered, but are not persuasive.

8. Applicant argues that Couvillon does not disclose an implant that is wirelessly powered since Couvillon discloses that the control unit 150 comprises a battery as a source of power. However, the Examiner notes that Couvillon discloses that "depending on the procedure time…a battery **can** be used as a source for power" (Column 12, lines 53-55, emphasis added). Such a disclosure indicates that a battery may be used, but

certainly does not require a battery. As such, it is the position of the Examiner that Couvillon does not require a battery to power the control unit 150.

9. Applicant further argues that Couvillon teaches away from wirelessly powering the device since Couvillon specifically discloses that the control unit comprises a power source that may comprise a battery. Couvillon's disclosure, though vague, does not rule out the possibility of the control unit being powered from an outside source. As such, it is the position of the Examiner, that taken together, the suggestion of using an outside signal to power the pumps of the Couvillon device and Couvillon's disclosure that the control unit comprises a power source, one could reasonably assume that the power for the control unit comes from a wireless source. As such, it is the position of the Examiner that the Couvillon disclosure, along with the other cited prior art, suggests the limitations of the claimed invention.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
9 November 2009